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Pabst Patent Group LLP
1545 PEACHTREE STREET NE
SUITE 320
ATLANTA, GA 30309

EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRANK A. SKRALY

Appeal 2010-004274
Application 10/661,939
Technology Center 1600

Before ERIC GRIMES, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, Administrative Patent Judges.

FREDMAN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a recombinant organism for producing polyhydroxyalkanoates. The Examiner rejected the claims as lacking written description and enablement. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

Statement of the Case

Background

The Specification teaches "methods and microbial strains suitable for producing PHA polymers or copolymers that avoids increasing the level of 3-hydroxyacid in the feed" (Spec. 3, ll. 27-29).

The Claims

Claims 16-23 are on appeal. Claim 16 is representative and reads as follows:

> 16. A recombinant organism selected from the group consisting of bacteria, yeast, fungi and plants for producing polyhydroxyalkanoates, comprising a heterologous gene encoding a CoA-dependent aldehyde dehydrogenase and a PHA synthase.

The issues

A. The Examiner rejected claims 16-23 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement (Ans. 3-5).

B. The Examiner rejected claims 16-23 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement (Ans. 5-8).

A. 35 U.S.C. § 112, first paragraph, written description

The Examiner finds that the "specification teaches the structure of only a single representative species of gene encoding CoA-dependent aldehyde dehydrogenase, three representative species of PHA synthase, single representative species of acyl-CoA transferase, single representative species of acyl-CoA synthetase, single representative species of β-ketothiolase and single representative species of acetoacetyl-CoA reductase"

(Ans. 4). The Examiner finds that given this lack "of description of representative species encompassed by the genus of DNAs used in the said recombinant organism, the specification fails to sufficiently describe the claimed invention" (Ans. 5).

Appellant contends that the

> enzymes defined by the claims are well-known, exist within well-defined classes of proteins, and the genes encoding them are known and described in the literature. The words "PHA synthase," and "Co-A-dependent aldehyde dehydrogenase["] classify proteins and readily convey distinguishing information concerning identity, via structure and function, such that one of ordinary skill in the art could easily visualize the identity of the members of each classification.

(App. Br. 8).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the claims fail to comply with the written description requirement?

Findings of Fact

1. The Specification teaches that "[c]oenzyme A-dependent aldehyde dehydrogenase is well known. For example, Jones and Turner reported in 1984 two studies on the detection and activities of CoA-dependent aldehyde dehydrogenase" (Spec. 9, ll. 13-15).

2. The Specification teaches that in "one embodiment, the CoA-dependent aldehyde dehydrogenase is encoded by the eutE gene of E. coli. Many other useful CoA- dependent aldehyde dehydrogenases are encoded by genes of other species such as described in Toth" (Spec. 9, ll. 17-20).

3. The Examiner finds that the Specification teaches "three representative species of PHA synthase" (Ans. 4).

4. Madison[1] teaches that "P(3HB) polymerase is just one member of the family of PHA polymerases. . . . Interestingly, there are only 15 fully conserved residues among the 26 known PHA polymerases" (Madison 27, col. 2).

5. Toth[2] teaches that CoA-acylating aldehyde dehydrogenase enzymes are found in four microbial species (Toth 4979, col. 1).

Principles of Law

"[T]he determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter." Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

Analysis

The Examiner finds that the "genus of polypeptides of any CoA-dependent aldehyde dehydrogenase and any PHA synthase used in making the claimed recombinant organism are structurally diverse as it broadly

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[1] Madison et al., Metabolic Engineering of Poly(3-Hydroxyalkanoates): From DNA to Plastic, 63 MICROBIOLOGY MOLECULAR BIOLOGY REVIEWS 21-53 (1999).

[2] Toth et al., The ald Gene, Encoding a Coenzyme A-Acylating Aldehyde Dehydrogenase, Distinguishes Clostridium beijerinckii and Two Other Solvent-Producing Clostridia from Clostridium acetobutylicum, 65 APPLIED ENVIRONMENTAL MICROBIOLOGY 4973-4980 (1999).

encompasses many mutants and variants comprising respective enzyme activity having different structures" (Ans. 11).

We think the instant situation is similar to that in Capon, where the prior art provided the underlying information regarding the members of the genus. The Specification provides extensive information regarding CoA-dependent aldehyde dehydrogenases, noting that these are well known enzymes (FF 1-2). The Specification also lists a number of CoA-dependent aldehyde dehydrogenase homologs on pages 9 and 10. The Examiner acknowledges that 3 PHA synthases are known (FF 3), and Madison teaches that 26 different members of this enzyme family are known (FF4). Toth teaches four CoA-dependent aldehyde dehydrogenases are known (FF 5).

As in Capon, the Appellant does not claim the inventive contribution is to provide sequences for a CoA-dependent aldehyde dehydrogenase and a PHA synthase. Instead, the inventive contribution is asserted to be the inclusion of a CoA-dependent aldehyde dehydrogenase which functions to reduce propionic acid toxicity by direct conversion of propionaldehyde to propionyl-CoA (see Spec. 8, ll. 8-10, 27-30). Capon teaches that the

> genes here at issue are prepared from known DNA sequences of known function. The Board's requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes.

Capon, 418 F.3d at 1358.

In our opinion, Capon controls the instant situation. The genes being claimed are the known enzymes of known sequence. This is not a situation where a single species is known and is used as representative of a larger, unknown, class. Here at least 26 different PHA synthases are known (FF 4), and at least 4 different CoA-dependent aldehyde dehydrogenases (FF 5). Thus, the instant situation is different than that in Ariad, for example, where the invention was drawn to an NF-κB inhibitor of which there was only, at best, a single example disclosed. See Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1356 (Fed. Cir. 2010).

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the claims fail to comply with the written description requirement.

B. 35 U.S.C. § 112, first paragraph - enablement

The Examiner finds that the "scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of aldehyde dehydrogenase gene (CoA-dependent), PHA synthase gene . . . broadly encompassed by the claims" (Ans. 6).

Appellant contends that the "examiner has failed to provide any evidence or reasoning as to why those skilled in the art would not extrapolate from the actual examples in the application to other aldehyde dehydrogenase . . . and PHA synthase genes from other sources that are known in the art as evidenced by disclosure in the specification" (App. Br. 18-19).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that undue experimentation would have been required to enable the full scope of the claims?

Principles of Law

"It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention." Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

Analysis

The Examiner provided no specific evidence that any particular embodiment was not enabled (see Ans. 5-8). Instead, the Examiner relied upon the general proposition that changes in the amino acid sequence of a protein will result in unpredictable changes to protein function (see Ans. 6). In In re Angstadt, 537 F.2d 498 (CCPA 1976), our reviewing court's predecessor explicitly recognized a situation where the relevant art was unpredictable, and that the claim at issue encompassed a number of inoperative embodiments. Id. at 502. The court nonetheless held that the claim, which encompassed using thousands of different catalysts, was enabled, in view of the Specification's disclosure of a large but finite list, and 40 working examples. See id. at 502-503.

We can agree with the Examiner's general proposition of unpredictability in altering enzymes but recognize that it does not apply to this particular situation. This is not a situation where the Appellant is claiming mutated proteins by function alone; indeed the Appellant does not specifically claim any mutations to the enzymes at all. The Examiner must

impute this breadth to the claim (Ans. 6). Instead, like Angstadt, this invention is drawn to the novel combination of two well known enzymes to alleviate a problem in polyhydroxyalkanoate synthesis in cells. Even assuming for argument's sake that the claim encompasses mutated enzymes which would not work in accordance with the claimed process, a claim does not lack enablement merely because it encompasses inoperative embodiments. See Angstadt, 573 F.2d at 502.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that undue experimentation would have been required to enable the full scope of the claims.

SUMMARY

In summary, we reverse the rejection of claims 16-23 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

We reverse the rejection of claims 16-23 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement.

REVERSED

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